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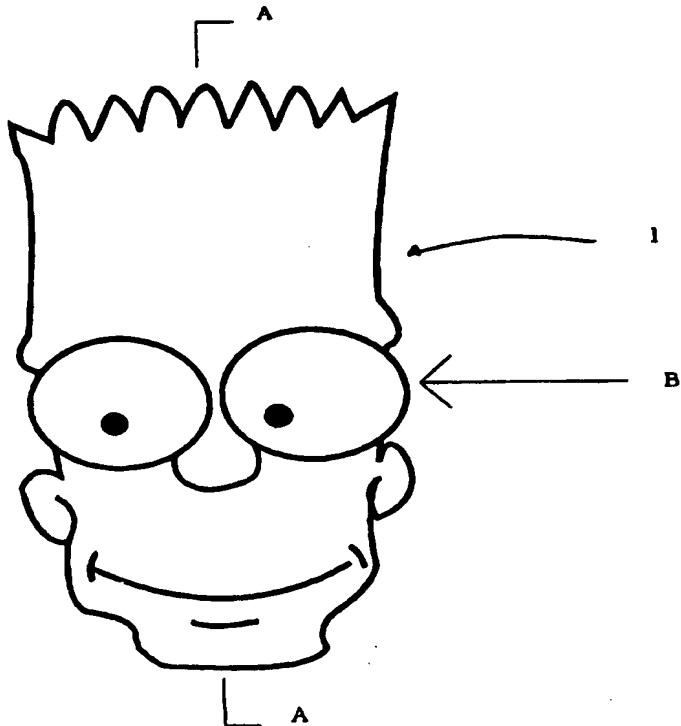
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| (51) International Patent Classification ⁶ : A61M 11/00, 15/00 | | A1 | (11) International Publication Number: WO 97/47344 (43) International Publication Date: 18 December 1997 (18.12.97) |
| (21) International Application Number: PCT/AU97/00371 (22) International Filing Date: 12 June 1997 (12.06.97) | | (81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW. ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). | |
| (30) Priority Data: PO 0379 12 June 1996 (12.06.96) AU PO 4235 17 December 1996 (17.12.96) AU | | Published <i>With international search report.</i> | |
| (71) Applicant (for all designated States except US): KAN GURU PTY. LTD. [AU/AU]; 1/30 Wangaratta Street, Richmond, VIC 3121 (AU). | | | |
| (72) Inventor; and | | | |
| (75) Inventor/Applicant (for US only): PARRY, Stuart [AU/AU]; 1/30 Wangaratta Street, Richmond, VIC 3121 (AU). | | | |
| (74) Agents: DI GIANTOMASSO, Frank et al.; Freehills Patent Attorneys, Level 47, 101 Collins Street, Melbourne, VIC 3000 (AU). | | | |

(54) Title: **METHOD AND DEVICE FOR FACILITATING THE USE OF MEDICAL APPARATUS BY PATIENTS**

(57) Abstract

The present invention provides a device to facilitate the use of a medical apparatus by a human patient, wherein the medical apparatus is to be inserted into an orifice of the patient's body, and wherein further, the device is adapted to cooperate with the medical apparatus, and comprises means to: (i) encourage the patient to use the medical apparatus; or (ii) reduce fear or apprehension on the part of the patient about using the medical apparatus.



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METHOD AND DEVICE FOR FACILITATING THE USE OF MEDICAL APPARATUS BY PATIENTS

Introduction

This invention relates to apparatus and methods to encourage human patients to use certain forms of medical apparatus, namely, those in which the apparatus, when used, is inserted into a bodily orifice. One application to which the invention is particularly (although not exclusively) applicable, is in relation to treatment of respiratory conditions, such as asthma, by apparatus used to inhale aerosol medications. The invention (and the background to it) will therefore be discussed in detail in the following description, with specific (but non-limiting) reference to the treatment of asthma, to which use it is particularly suited.

Background to the invention

Asthma is a form of allergy that is particularly prevalent throughout the global community. In the United States alone, it is estimated that approximately 20 percent of the child population suffers from some form of allergy. Asthma is one of the more chronic illnesses of childhood, which is estimated to affect more than 3 million children in the United States alone. Allergies and asthma are leading causes throughout the world of school absenteeism, accounting in the United States alone, for more than 125 million lost school days annually. The impact of allergic conditions (such as asthma) upon children is demonstrated not only in terms of their absences from school, but also in the lack of participation of child asthma sufferers in other activities, such as sports and exercise programs. Additionally, in some cases, allergies or asthma can bring about a life threatening crisis for a child (or for that matter, an adult) patient.

Modern medicine provides many pharmacological agents which can be used to treat asthma. Typically, the pharmacological agents used to treat conditions such as asthma include the beta-adrenoceptor agonists, such as salbutamol and substances having a similar pharmacological action. Such agents can be administered to a patient by an inhaler, in which the pharmaceutical agent is included in an aerosol formulation. Portable, hand-held aerosol devices for use in delivering medication for bronchitis, asthma and similar ailments are known and are frequently prescribed by medical practitioners treating patients who suffer from such conditions. Frequently, the dosage regimen prescribed to a patient suffering from one of those conditions involves several daily inhalations of the medication, from the hand-held aerosol administrator.

While in concept, the use of such devices should provide a convenient means for treating asthma, bronchitis or similar ailments, the medical literature is replete with data which show that patient compliance with a medically advised course of treatment is poor, and constitutes a serious community health problem. Many studies have shown that patients suffering from such conditions (and particularly, children) frequently fail to comply with a course of treatment advised to them by their physician, for reasons which are not entirely understood. In the case of children in particular, the failure to comply with a course of treatment is likely to be due to factors such as (i) fear on the part of the child about using a medical apparatus, such as an inhaler, (ii) embarrassment or self-consciousness on the child's part about using an inhaler in the company of other persons such as, in particular, the child's peers, and (iii) unpleasant associations that a child may have, with medical treatment or illness in general. These problems are not of course confined to children, and they also apply to adult patients suffering from conditions such as those mentioned above. The present invention attempts to overcome one or more problems of the prior art mentioned above.

General disclosure of the invention

The invention generally provides a device to facilitate the use of a medical apparatus by a human patient, wherein the medical apparatus is to be inserted into an orifice on the patient's body, the device being adapted to co-operate with the medical apparatus and including means to

- (i) encourage the patient to use the medical apparatus; or
- (ii) reduce fear or apprehension on the part of the patient about using the medical apparatus.

The patient may be either an adult or a child. In this specification, the term "adult" means a person who is aged 18 years or older, and the term "child" means a person aged under 18 years.

The medical apparatus is constructed in accordance with the use for which it is intended. The orifice into which the medical apparatus is to be inserted will generally be the patient's mouth, although the orifice may be a nasal, aural or other bodily opening.

Preferably, the means for encouraging the use of, or for reducing fear or apprehension on the patient's part about using the medical apparatus, include providing an image on the device with which the patient has favourable psychological associations. Such an image

could take the form of the head or face of an actual or fictitious person or a fictitious character represented on the device. In a preferred form, the device would assume the three-dimensional configuration of the face or head of such a person or character. In two particularly preferred forms of the invention, the device either includes a representation of 5 the head or face of a cartoon character which appears on an external surface of the device, or even more preferably, the device visually assumes the three-dimensional configuration of the head or face of such a character.

The co-operation of the device with the medical apparatus may be achieved by forming the 10 device integrally with the medical apparatus, or alternatively, by the device taking the form of an accessory or auxiliary structure to it. In one embodiment of the invention, the medical apparatus is an inhaler for use in delivering inhaled medications for treating respiratory complaints, such as asthma. In such an embodiment, the device could be a 15 three-dimensional representation of a cartoon character's head formed integrally with the inhaler, so as to provide an inhaler whose use would be more readily adopted by, for example, children. Alternatively, and as explained earlier, the device could take the form of an accessory having the form of a cartoon character's head so as to provide a cover for the inhaler, and wherein the inhaler could be inserted into the cover.

The invention further provides a method for facilitating the use of a medical apparatus by a 20 human patient, wherein the medical apparatus is to be inserted into an orifice on the patient's body, including the steps of:

- (a) adapting the device to co-operate with the medical apparatus; and
- (b) providing means on or for the device to:
 - (i) encourage the patient to use the medical apparatus; or
 - (ii) reduce fear or apprehension on the part of the patient about using the 25 medical apparatus.

Brief description of the drawings

The invention will now be described by way of example only, and with reference to the accompanying drawings, in which:

30 Fig. 1 represents a front view of a device constructed in accordance with a first embodiment of the invention; and

Fig. 2 represents a rear view of the device depicted in Fig. 1;

Fig. 3 represents a longitudinal section of the device shown in Figs. 1 and 2, along the line A-A, and when viewed in the direction of the line B shown in Fig. 1;

Fig. 4 represents a side view of the device;

5 Fig. 5 represents a front view of a further embodiment of the invention; and

Fig. 6 represents a side view of the embodiment shown in Fig. 5.

Detailed description of the preferred embodiments

Referring now to the drawings, Figs. 1 - 4 depict a device constructed in accordance with the invention, to facilitate the use of a medical apparatus (in the form an inhaler for an aerosol formulation of a pharmaceutical agent) to treat a respiratory ailment, such as asthma. As can be seen, the device (generally denoted 1 in the accompanying drawings) generally has the appearance of the head of a fictional character, and in the embodiments shown, is the popular cartoon character known as "Bart Simpson"™ from the television series called "The Simpsons"™. The device 1 is shown in the form of an accessory to act 10 as a cover for a hand-held inhaler (of conventional design) 3. As shown more particularly in Fig. 3, inhaler 3 is capable of co-operating with the device 1 by being inserted into the opening 5 at the upper end of device 1. Thereafter, inhaler 3 is moved into position within device 1 so that the mouth piece 7 (and any covering cap for it) may protrude generally from the rear opening 9 of the device. When so positioned, device 1 can be conveniently 15 be held by a user of the inhaler, so as to inhale a dose of a pharmaceutical agent contained within the inhaler 3.

In the embodiment of the invention shown in Figs 1 - 4, device 1 therefore includes means (in the form of configuring the device so as to resemble the head of the popular cartoon character "Bart Simpson"), so as to encourage persons suffering from asthma (or some 20 other ailment which can be similarly treated by the use of an aerosol inhalation device for administering a medication), which either:

- (i) encourages the use of the medical apparatus (ie, the inhaler) by the intended patient;
 - or
- (ii) reduces fear or apprehension on the part of the patient, with respect to using the 30 medical apparatus.

It is believed that a device such as the one shown in the embodiment of the invention depicted in Figs. 1 - 4 of the accompanying drawings, would be particularly attractive to

children, who would generally form a favourable psychological association with the image used, namely, in the embodiment shown, a representation of the head of the popular cartoon character "Bart Simpson"™.

A further embodiment of the invention is shown in Figs. 5 and 6, in which a different image to the one shown in the embodiment represented in Figs. 1 - 4 is depicted. In the second embodiment of the invention, the image used in the device is a representation of the head of the cartoon character "Homer Simpson"™, also from the "The Simpsons"™ television program. The general configuration of the device in the second embodiment shown in Figs. 5 and 6 of the accompanying drawings is essentially similar to that depicted in the first embodiment (shown in Figs. 1 - 4). In each of the embodiments shown in the accompanying drawings, the device 1 generally takes the form of a cover into which an inhaler for an aerosol formulation of a pharmaceutical agent can be inserted. In other words, in these two embodiments, the invention takes the form of an accessory or auxiliary structure to the medical apparatus. As explained earlier however, the device of the invention could also be formed integrally with the medical apparatus whose use by a patient it is designed to encourage. For example, the device could be integrally formed with an inhaler for delivering a dose of an aerosol formulation of a pharmaceutical agent. The manufacture of composite articles of this nature would be comprehended by those skilled in the art of such manufacturing techniques. Where however, it is desired to form the device as an accessory or auxiliary structure for use in co-operation with the medical apparatus, it would be possible to manufacture the device by any suitable means, including particularly the technique known as "rotational moulding". Such a technique would be particularly suitable for forming the device from a plastics material. Those of ordinary skill in the art of manufacturing such items would readily comprehend the nature of the techniques that could be used to manufacture them. Many techniques other than rotational moulding of plastics materials could conveniently be used for that purpose, as would be comprehended by those skilled in that art.

Although the two embodiments of the invention described above (and depicted in the accompanying drawings) feature an image which takes the form of a representation of the head of a cartoon character, the image used in any particular application could take any number of forms. For example, the image could take the form of a representation of the head (or for that matter, the entire body) of an actual person, or a fictitious person or

character. Additionally, the image could take any number of other forms, including representations (whether real or fictionary) of animals, vehicles, cartoon characters other than those expressly disclosed herein, or indeed any other image with which the patient would have a favourable association. For example, teenage users of inhalation devices for delivering asthma medications might feel self-conscious about using an inhaler by itself, but might be encouraged to use an inhaler in conjunction with a device containing a popular image (such as an actual or simulated image of a popular rock music musician or sporting personality). The choice of image used in any application could therefore depend upon the age of the user, and the user's likely beliefs, as well as other factors. All such images are comprehended by the spirit and scope of the present invention.

The device is capable of being used with many forms of medical apparatus which are for insertion into an orifice in the human body. For example, a device constructed in accordance with the invention could be used in cooperation with a thermometer, a peak flow meter (for measuring the forced expiratory volume exhaled by a patient, and typically which is used to measure the lung capacity of asthma sufferers), an auroscope, or indeed any other medical apparatus for insertion into an orifice of the human body, whose use by the patient might otherwise be impaired in the absence of concomitant use of the device of the present invention.

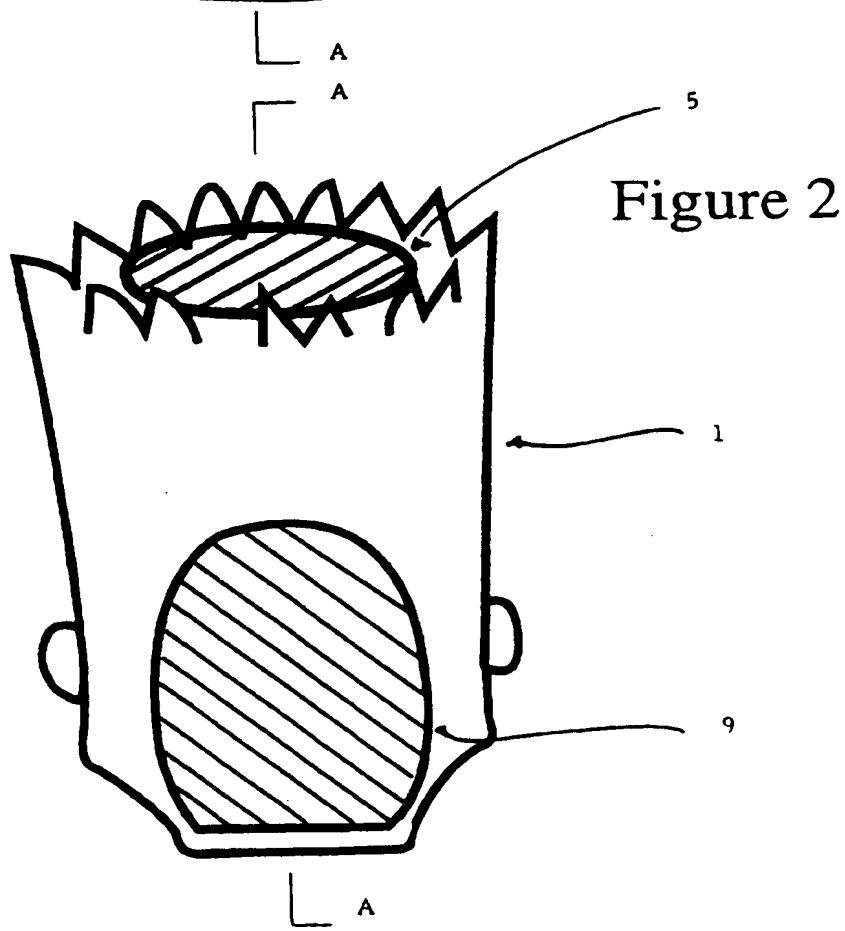
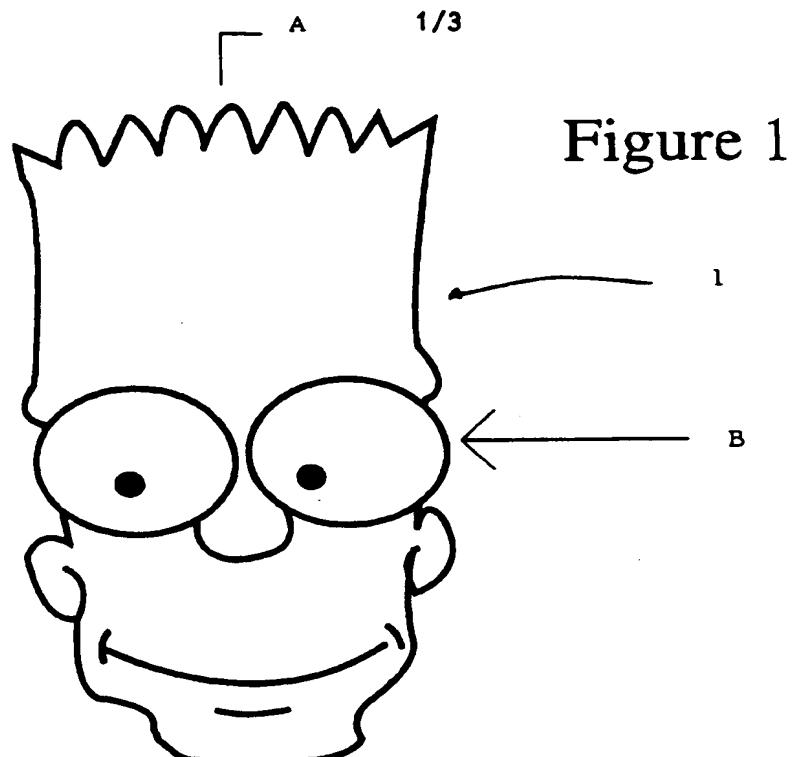
It is therefore to be understood that the apparatus and the method provided by the invention are each capable of many modifications and/or variations, and could be put to many different uses. The apparatus and method of the invention are therefore by no means limited to the particular details of the preferred embodiments described above, and that the spirit and scope of the invention extends to each novel feature and combination of features described in this specification.

It will be understood that the term "comprises" or its grammatical variants as used herein is equivalent to the term "includes" and is not to be taken as excluding the presence of other elements or features.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device to facilitate the use of a medical apparatus by a human patient, wherein the medical apparatus is to be inserted into an orifice of the patient's body, and wherein further, the device is adapted to cooperate with the medical apparatus, and comprises means to:
 - (i) encourage the patient to use the medical apparatus; or
 - (ii) reduce fear or apprehension on the part of the patient about using the medical apparatus.
- 10 2. A device as claimed in claim 1, in which the means for encouraging the use of, or for reducing fear or apprehension on the patient's behalf about using the medical apparatus, comprise providing an image on the device, with which the patient has favourable psychological associations.
- 15 3. A device as claimed in either of claims 1 or 2, in which the image is represented in two dimensions on an external surface of the device.
4. A device as claimed in either of claims 1 or 2, in which the image is represented three-dimensionally on the device.
- 20 5. A device as claimed in any one of the preceding claims, in which the image takes the form of the whole or part of the body of an actual or fictionay person or character represented on the device.
6. A device as claimed in claim 5, in which the image takes the form of the head or face of the actual or fictionay person or character.
7. A device as claimed in any one of claims 1 to 4, in which the image takes the form of part, or the whole of the body of an animal represented on the device.
- 25 8. A device as claimed in claim 7, in which the image takes the form of the head or face of the animal.
9. A device as claimed in any one of claims 1 to 4, in which the image takes the form of an object represented on the device.
10. A device as claimed in any one of preceding claims, in which the cooperation of the device with the medical apparatus is achieved by forming the device integrally with the medical apparatus.

11. A device as claimed in any one of claims 1 to 9, in which the cooperation of the device with the medical apparatus is achieved by the device taking the form of an accessory or auxiliary structure to the medical apparatus.
12. A device as claimed in any of the preceding claims, in which the medical apparatus is for insertion into the patient's mouth, or a nasal or aural orifice on the patient's body.
13. A device as claimed in claim 12, in which the medical apparatus is for use in the treatment of a respiratory medical condition.
14. A device as claimed in claim 13, in which the medical apparatus is an inhaler for use in delivering inhaled medications for treating respiratory medical conditions.
15. A device as claimed in any of the preceding claims, in which the patient is a person under the age of 18 years.
16. A device as claimed in any of the preceding claims, in which the patient is a person aged 18 years or more.
- 15 17. A method for facilitating the use of a medical apparatus by a human patient, wherein the medical apparatus is to be inserted into an orifice of the patient's body, including the steps of:
 - (a) adapting the device to cooperate with the medical apparatus; and
 - (b) providing means on or for the device to:
 - (i) encourage the patient to use the medical apparatus; or
 - (ii) reduce fear or apprehension on the part of the patient about using the medical apparatus.



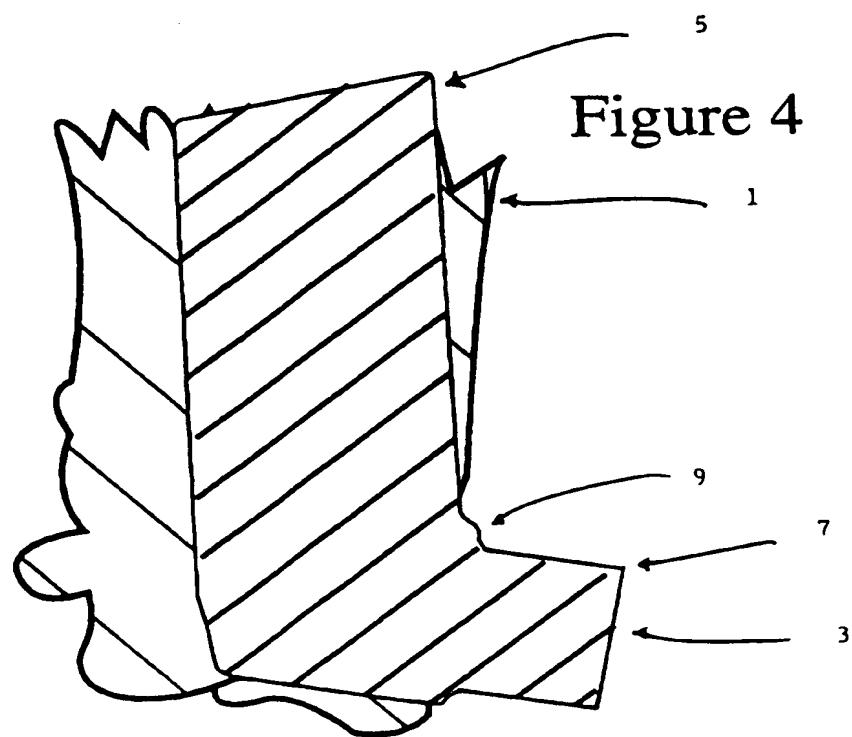
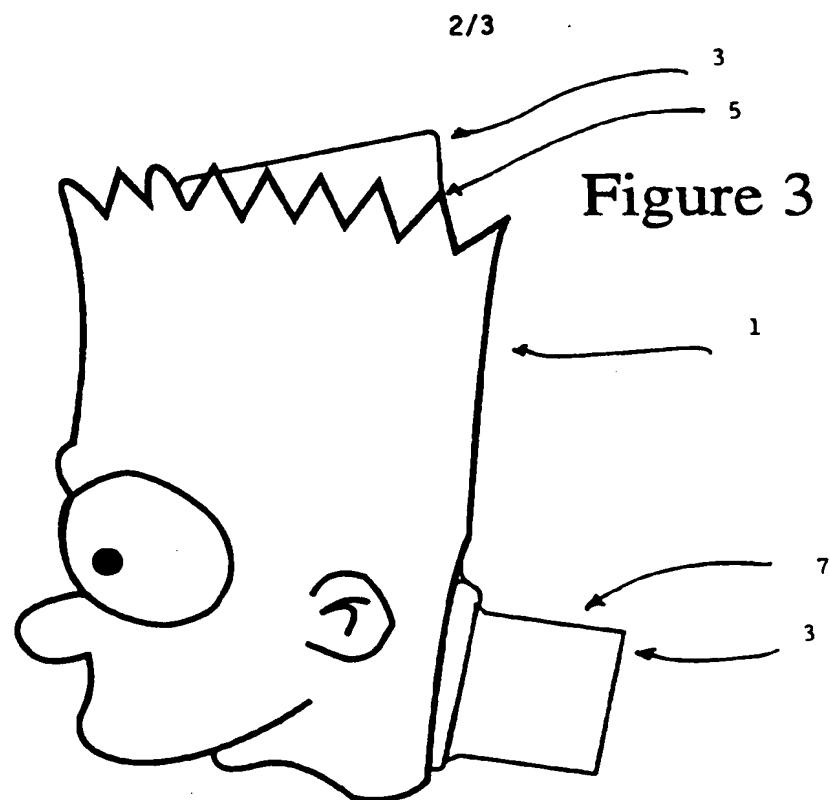


Figure 5

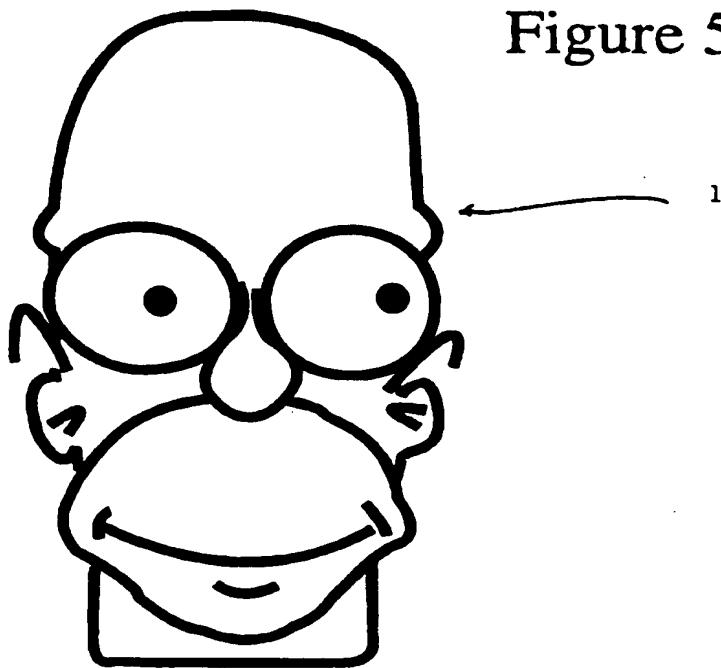
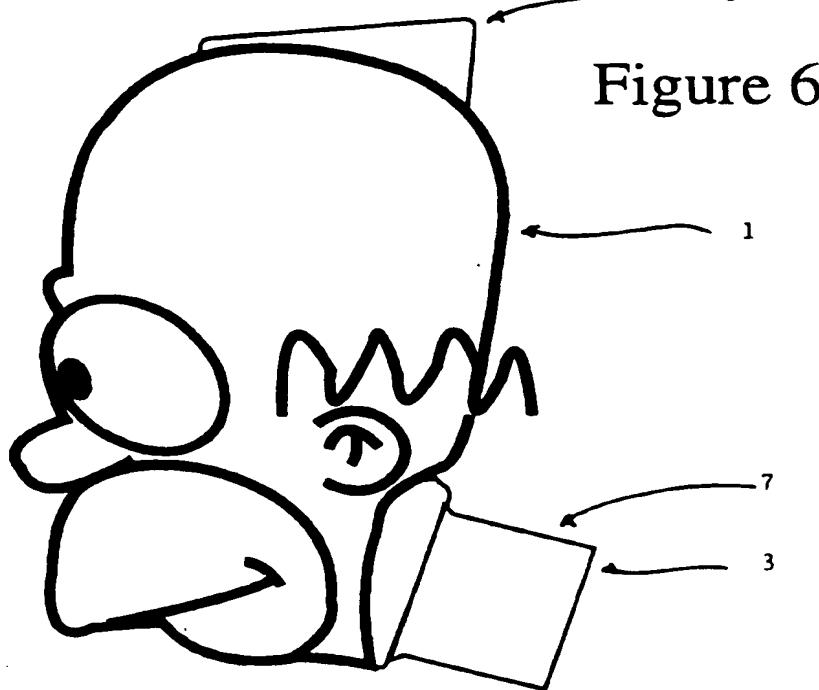


Figure 6



INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00371

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| A. CLASSIFICATION OF SUBJECT MATTER | | |
| Int Cl ⁶ : A61M 11/00, 15/00 | | |
| According to International Patent Classification (IPC) or to both national classification and IPC | | |
| B. FIELDS SEARCHED | | |
| Minimum documentation searched (classification system followed by classification symbols) IPC : A61M 11/00, 15/00 | | |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU : IPC as above; designs class 24-04,09-07A | | |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT JAPIO | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | WO,A 90/07945 (CPP CONSULT PRODUCTION PATENTVERWERTUNGS ESELLSCHAFT MBH) 26 July 1990 Entire document | 1-9, 11-17 |
| P,X | WO,A 96/26755 (MARR) 6 September 1996 Page 2 lines 13 - page 3 line 11, page 5 lines 11-21 | 1-9, 11-17 |
| X | EP,A 372892 (ROSEIRO) 13 June 1990 Column 3 line 52 - column 4 line 30 | 1-12, 15-17 |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C | | <input checked="" type="checkbox"/> See patent family annex |
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| Date of the actual completion of the international search 10 July 1997 | Date of mailing of the international search report 05 AUG 1997 | |
| Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (06) 285 3929 | Authorized officer JOHN HO Telephone No.: (06) 283 2329 | |

INTERNATIONAL SEARCH REPORT**International Application No.
PCT/AU 97/00371**

| C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|---|---|----------------------------------|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | US,A 3299891 (SMETON) 24 January 1967 Entire document | 1-12, 15-17 |
| X | AU,B 231010 (39809/58) (THE BRITISH OXYGEN COMPANY LTD.) Page 2 line 32-40 | 1, 10-17 |
| X | US,A 5228595 (BOOKER) 20 July 1993 Column 4 lines 6-38 | 1-12, 15-17 |
| X | US,A 5312187 (CHIU) 17 May 1994 Figures 1, 7-8 | 1-12, 15-17 |
| P,X | US,A 5620462 (VALENTI) 15 April 1997 Column 2 lines 11-27 | 1, 10-12, 15, 17 |
| X | US,A 5172863 (MELONE et al) 22 December 1992 Entire document | 1-9, 11-13, 15-17 |

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No.
PCT/AU 97/00371

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| Patent Document Cited in Search Report | | Patent Family Member | | |
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| US | 5172863 | | | |
| US | 5620462 | | | |
| US | 5312187 | | | |
| US | 5228595 | | | |
| EP | 372892 | BR | 8906259 | PT |
| WO | 9626755 | AU | 47295/96 | |
| WO | 9007945 | DE | 3900863 | |

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